K133045

510(k) Summary

APR 10 2014

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___03/13/2014____

1. Submission Applicant:

Infopia Co., Ltd.
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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
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3. Device:

▪ Device's Trade Name:	Element™ Lite Blood Glucose Monitoring System
▪ Device's Common Name:	Blood Glucose Test System Quality control material (assayed and unassayed)
▪ Device's Classification Name:	Glucose oxidase, glucose Single (specified) analyte controls Calculator/data processing module for clinical use
▪ Classification Regulation:	21CFR 862.1345 21CFR 862.1660
▪ Classification Product Code:	CGA, NBW, JJX

4. Predicate Device:

Element™ Blood Glucose Monitoring System (K113670) by Infopia Co., Ltd.

5. Description:

The Element™ Lite Blood Glucose Monitoring System consists of a meter, test strips and control solutions (level 1, level 2 and level 3), a lancing device and sterile lancets. This blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

6. Indications for use:

The Element™ Lite Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The Element™ Lite Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element™ Lite Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Element™ Lite Test Strips are for use with the Element™ Lite Meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The Element™ Lite Control Solutions are for use with the Element™ Lite Meter and Element™ Lite Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

7. Technological Characteristics:

The Element™ Lite Blood Glucose Monitoring System has the same fundamental scientific technology as the predicate device and has similar performance specifications and features.

8. Performance Data:

The performance tests for the Element™ Lite Blood Glucose Monitoring System were performed in accordance with ISO 15197:2003 and some other international standards. Clinical evaluation included method comparison, user performance and alternative-site blood glucose measurement. Non-clinical performance evaluations were conducted to establish the performance, functionality and reliability characteristics of the Element™ Lite Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 1,098 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusion:

Infopia Co., Ltd. concludes that the Element™ Lite Blood Glucose Monitoring System is safe and effective and also substantially equivalent to the predicate device, Element™ Blood Glucose Monitoring System (K113670).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133045

Device Name
Element™ Lite Blood Glucose Monitoring System

Indications for Use *(Describe)*

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

INFOPIA CO., LTD.
C/O PRISCILLA CHUNG
2651 E. CHAPMAN AVE STE. 110
FULLERTON CA 92831

Re: K133045
Trade/Device Name: Element™ Lite Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: September 24, 2013
Received: September 27, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Katherine Serrano -S